REMARKS

Claims 1-5, 9, 10, 12, 14-18, 20-22, 24–30, 34-37, 39, 40, 42, 45-49 are pending in this application and are rejected under 35 USC §112, first paragraph, for allegedly not satisfying the written description requirement or the enabling requirement.

Applicants maintain that there is written description for the aryl ureas claimed, even those with groups defined by the phrase, "a carbon based moiety of up to 24 carbon atoms optionally containing heteroatoms selected from N, S, and O." While the scope of the moieties defined by this language is broad, this scope is finite in that the moieties are limited in size (up to 24 carbon atoms) and composition (carbon based, optionally having N, S and O atoms). When considering the preferred embodiments of certain groups defined by this phrase, (e.g. alkyl, alkoxy, cycloalkyl, heterocyclic, alkenyl, alkenoyl, aryl, hetaryl, aralkyl and alkaryl for R_y, R_x, R_a, R_b and R_z), one skilled in the art would clearly recognize the chemical bonds and configurations for the atoms within these moieties are conventional and well known in the art. Therefore, when considering the disclosure as a whole, one skilled in the art could determine which aryl ureas fall within the scope of this invention and they would recognize that applicants had possession of the full scope of aryl ureas defined by this language based on the broad scope of the preferred species and the broad scope of moieties illustrated for R_a and R_b in the examples supporting this language.

Claims 2, 16, 17, 34-37, 39, 40, 42, 45-49 define aryl ureas without relying on the phrase, "a carbon based moiety of up to 24 carbon atoms optionally containing heteroatoms selected from N, S, and O." Since no evidence has been presented to support the allegation that these claims fail to satisfy the written description requirement of 35 USC §112, applicants submit the rejection of these claims should be withdrawn.

The specification clearly provides an enabling disclosure for the aryl ureas claimed, the pharmaceutical compositions that contain them and the treatment methods that use them for the reasons stated in the previous reply. In fact, the specification provides more than it needs to in satisfying the requirements of 35 USC §112, e.g., in *vitro* raf kinase assays (and IC_{50} data) and in *vivo* assays (see pages 105 and 106) for testing the activity of the claimed

compounds. By performing the same or similar routine tests, one of ordinary skill in the art can determine the activity levels of each of the claimed compounds in treating various cancers. No evidence has been presented that the disclosure fails to meet the enablement requirement under 35 USC §112, first paragraph, and so the rejection should be withdrawn.

It is alleged that evidence to support the rejection is present based on the observations that the claims cover a "wide range of compounds," that "the state of the prior art is that the drugs and the enzymes react in a lock and key mechanism and the structure of the compound has to be specific" and that "the pharmaceutical art is unpredictable."

Assuming, for the sake of argument, that these observations are true, they do not provide any evidence that the compounds claimed are not enabled by the disclosure. While the definition of certain moieties on the claimed compounds is broad, such as those defined as, "a carbon based moiety of up to 24 carbon atoms optionally containing heteroatoms selected from N, S, and O," the compounds claimed all fall within a class of diaryl ureas. No evidence has been presented that diaryl ureas compounds, as a group, are not sufficiently specific to have pharmaceutical activity. As shown by the prior art of record, many diaryl ureas have pharmaceutical activity. The diaryl ureas claimed have structural features which make them novel and unobvious over the diaryl ureas known in the art and no evidence has been presented that diaryl ureas with these novel and unobvious structural features are not defined with sufficiently specificity to have the pharmaceutical activity disclosed in the specification and be enabled by this disclosure.

The diaryl ureas claimed have groups "A" and "B" positioned on each side of the urea group. Group "A" has the structure: $-L(M-L^1)_q$, which is: —phenyl—M—(phenyl or 5-6 membered hetaryl)$_q$ .Group "B" is pyridyl, quinolinyl or isoquinolinyl. The compounds claimed are further defined as having a required substituent on the group L^1 ", which is - SO_2R_x, $-C(O)R_x$ or $-C(NR_y)R_z$. No evidence has been presented that any of these specific diaryl ureas would not be an active in treating solid tumors.

While moieties on the claimed compounds have been broadly defined, no evidence has been presented that the definition of these moieties encompasses inoperative compounds.

In fact, the compounds illustrated in the examples show that raf kinase inhibition is retained with significant variation in two of the broadly defined moieties, R_a and R_b. For those compounds not illustrated in the examples, it would be routine for one skilled in the art to test the compound using one of the assays disclosed in the specification. The enablement requirement is satisfied if, given what those of ordinary skill in the art already know, the specification teaches those in the art enough that they can make and use the claimed invention without undue experimentation. See *Amgen v Hoechst Marion Roussel*, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003).

As discussed above with regard to the rejection based on written description, claims 2, 16, 17, 34-37, 39, 40, 42, 45-49 define aryl ureas without relying on the phrase, "a carbon based moiety of up to 24 carbon atoms optionally containing heteroatoms selected from N, S, and O." Since these claims do not contain the language objected to and no other reasons have been presented to reject these claims for failure to satisfy the enablement requirement of 35 USC §112, applicants submit the rejection of these claims should be withdrawn.

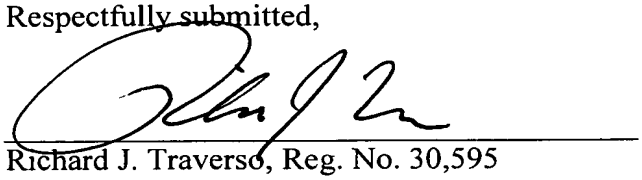
For the reasons indicated above, applicants submit that all pending claims meet the requirements of 35 U.S.C. § 112, first paragraph and that the PTO has failed to meet its burden of establishing that the disclosure does not enable one skilled in the art to make and use the compounds, compositions and methods recited in the claims, such that this rejection should be withdrawn.

Double Patenting

Applicants maintain the claims herein define compounds which are patentably distinct from those claimed in cited copending applications for the reasons stated in the last response. In addition, Applicants maintain these rejections are premature. Applicants will address these rejections in greater detail when allowable subject matter is identified in this application.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Richard J. Traverso, Reg. No. 30,595
Attorney/Agent for Applicants

MILLEN, WHITE, ZELANO &
BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: **BAYER-0015-P03**

Date: **August 30, 2006**